Surveillance of Marketed Products: Home Use

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Surveillance Objectives

- Ensure reasonable safety and effectives of medical devices
- Identify and prevent the occurrence of adverse events
- Identify the causes of problems when harm does occur
- Capture data and information to better inform decision makers

Information Sources

- Medical Device Reporting (MDR)
- Medical Device Surveillance Network (MedSun)
- Epidemiologic Research
- Postmarket Studies
- Collaborations and Partnerships

Medical Device Reporting

- Manufacturers are required to report device related deaths, serious injuries, and certain malfunctions within 30 days of "becoming aware"
- Receive over 200k individual reports per year
- Receive over 200k summary reports
- Over 90% of the reports are from manufacturers

MDR Review

- Reports are reviewed to identify immediate or potential risk to public health
  - Unexpected risk either new or at increased level
  - User error
  - Problems across device type
  - Problem not corrected by the manufacturer

User Facility Reporting

- User facilities are required to report device related deaths to FDA; deaths and serious injuries to the manufacturer
- Very small number of reports received from user facility reporting
- Small number of reports outside of the MedSun program

Medical Device Surveillance Network (MedSun)

- Network of 350 user facilities
- Real time reporting from clinical users
- Sites specifically trained in medical device adverse event reporting
- Partnership with robust sharing of safety information
- Emphasis on prevention
- Human factors focus

MedSun

- Real time information for decision making: reports, surveys,
- Reports of near misses or close calls
- Subnetworks: KidNet, LabNet, HeartNet, HomeNet
- Regional Rep program to support MedSun participation (pilot)

Home Net

- 26 sites enrolled in HomeNet
- 14 reports submitted between 9/08 and 5/10 from 7 different sites
- Infusion pumps, pulse oximeters, beds, syringe pump, PICC catheter, negative pressure wound therapy, apnea monitor
- Ongoing efforts to increase reporting to HomeNet and consider other strategies

Barriers to Better Information

- MDR data: difficult to tell if it is really a home use issue
- Underreporting
- Reports generally not very complete
- Challenge to get back to the reporter
- Knowledge skills and ability to recognize event may be device related

Barriers to Reporting

- Knowledge gap between recognizing device related events and then taking action to report
- Home care nursing/assistant turnover
- Benefits of reporting not apparent
- Home health care agencies have different policies and procedures

Postmarket Studies

- Condition of Approval Studies: studies mandated as part of the approval of high risk devices

- Postmarket Surveillance Studies: products on the market where additional information is needed to address a safety concern

Epidemiological Research

- Population studies in real world use situations
- Use registries, observational databases and other surveillance systems

Collaborations

- Academic partners
- Professional organizations
- Other Government Agencies
- Active, targeted, consumer groups